



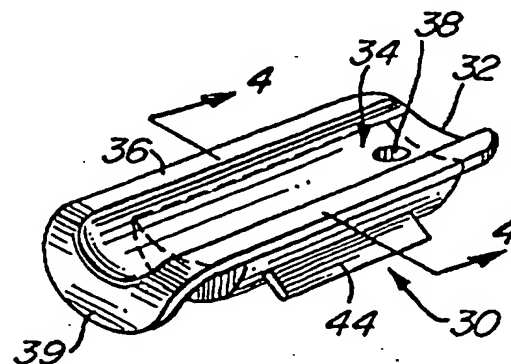
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(54) Title: PATELLO-FEMORAL JOINT REPLACEMENT DEVICE AND METHOD

(57) Abstract

A prosthetic system comprising a patellar unit to replace the femoral surface of the patella with a convex prosthesis constructed from a low-friction material and an elongate femoral prosthesis for replacing the trochlear groove without use of bone cement. The femoral prosthesis has an arcuate indentation on its upper surface to accommodate the patellar prosthesis and a lower surface with diverging, protruding vanes. The lower surface and the vanes are made of a biocompatible material that promotes bonding to living bone. The femoral prosthesis is inserted by first driving a guide rod into the distal end of the femur. Then a guide frame is inserted onto the rod to guide an instrument in the cutting of a groove in the trochlear portion of the femur. Then a second guide frame replaces the first guide frame and acts as a template for cutting slots sized to receive the vanes of the prosthesis. Finally, the guide frame and rod are removed, and the prosthesis is slid into the cut groove with the vanes occupying the slots. The prosthesis is fixed in place by an insertable peg with no use of bone cement. Over time the interaction of the bone with the vanes results in tight integration of the prosthesis so that it cannot not be loosened.



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PATELLO-FEMORAL JOINT REPLACEMENT DEVICE AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to prosthetic replacements of joints and, more specifically, to an implantable patello-femoral joint prosthesis and method for its insertion.

2. Description of Related Art

Although joints of the human body are miraculous mechanical devices often lasting a lifetime with no added lubrication or service, our joints, like any mechanical or biological structure, are subject to certain failures. The joints are naturally lubricated and cushioned by synovial membranes and cartilages so that they normally appear subject to little wear. Part of this apparent lack of wear is doubtless due to living tissue's ability of regeneration and self-repair. However, joints are not invincible. Sometimes the body's immune system goes awry and attacks a joint, thereby damaging it irreversibly (rheumatoid arthritis). Sometimes old age and general wear and tear catches up with the joint's biological repair system (osteoarthritis). Sometimes a sharp blow or overextension of the joint results in mechanical damage that cannot be repaired by the normal healing process.

The knee joint is a frequent place for joint damage, and inability to walk normally is a frequent result of such damage. The knee is a common source of problems because the joint has an unusually large range of motion and bears half the weight of the entire body. A primary knee movement is the bending and straightening of the leg in which a lower part of the leg (tibia and fibula bones) flex in relation to an upper part of the leg (femur bone). The knee joint flexes over almost 180 degrees from a kneeling position, where the upper and lower leg are almost parallel to each other, to a straight position, where the upper and lower leg form essentially a straight line. The knee joint can also accommodate a certain amount of rotary motion in which the lower leg rotates a few degrees in relation to the upper leg.

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This wide range of motion requires extensive contact surface between the femur and the tibia. The joint is rather loosely held together by tendons and ligaments to permit such a wide range of motion. A front-facing side of the knee joint is protected by a separate knee cap (patella) which is held in place by ligaments and slides on a femoral joint surface (trochlear groove) as the knee bends. The patella and its ligaments are mechanically involved in joint extension. If any of the joint surfaces (femoral surface, patellar surface, or tibial surface) becomes damaged or roughened, the knee joint will not operate properly.

10 A common problem is damage to the patello-femoral joint so that free motion of the patella is inhibited and painful. This "runner's knee" can make normal joint movement almost impossible. At one time, before the mechanical and protective functions of the patella were understood, the patella was simply removed in an attempt to cure patello-femoral problems.

15 Today a variety of prosthetic replacements have been developed for different joint surfaces of the knee joint. In extreme cases the entire joint can be replaced with a prosthetic device. However, such surgery naturally requires a considerable time for recovery. In less extreme cases it may be advantageous to replace only the damaged part of the joint. The present invention is concerned with such a replacement for the patello-femoral joint. This type of knee surgery is less drastic than a complete replacement of the knee and is designed for patients whose main problems involve only the patello-femoral part of the knee, and is directed to providing a smooth replacement surface on the femur on which the patella "rides."

25 There are a number of prior art devices which have attempted to solve the problem of replacing the trochlear groove, or in some way attempted to solve problems due to improper interaction of the patella and femur. United States Patent No. 3,806,961 to Müller shows a prosthesis in which an annular sector having a guide groove is implanted into the end of the femur. A raised arcuate runner member is implanted into the patella so that the patella can slidably move in the guide groove with the runner member acting as a bearing surface. The prostheses are attached to the bone surfaces by bone cement. A basic problem with bone cement is that it is often not permanent. A layer of inflammatory tissue forms between the bone and the cement so that the implant eventually loosens and requires replacement. The relatively short life of joint prostheses has generally limited their use to older patients whose projected life span is too short for a likelihood of prosthesis replacement.

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United States Patent No. 3,878,566 to Bechtol discloses another patellar prosthesis. Here a femoral implant bears a more or less acute groove, and the patellar component bears a somewhat crest-like ridge projection that rides in the groove. Again, the devices are fixed in place with bone cement, although they also bear ridged pegs designed to allow improved bone adhesion.

5 United States Patent No. 4,007,495 to Frazier uses a slightly different approach. The patellar component rides in a femoral groove, but the system is also equipped with a femoral projection that engages a slot in the patellar implant. While this structure prevents separation of the patella from the femur, it also greatly restricts movement of the patella and may result in unnatural joint action. Again, this prosthesis is attached by bone cement and ridged pegs.

10 United States Patent No. 4,151,615 to Hall provides a femoral component and a patellar component that more closely approximate natural patello-femoral joint motion. However, this device also relies on bone cement for adherence to the bones of the joint. United States Patent No. 4,838,891 to Branemark et al. addresses the adhesion problems of prior prostheses by providing a two-part system where an anchoring device is inserted during a first operation. After the healing process fixes the anchoring device firmly in place, a second operation inserts the weight-bearing part of the prosthesis which engages the anchoring device. However, this system requires multiple operations even to insert a patello-femoral prosthesis—a prosthesis designed to be used in relatively uncomplicated cases.

OBJECTS AND SUMMARY OF THE INVENTION

25 It is an object of the present invention to provide a patello-femoral replacement device that allows essentially normal movement of that joint;

It is another object of the present invention to provide a prosthesis with improved adherence to the bone without the use of bone cement so that the prosthesis may be used on young patients; and

30 It is a further object of the present invention to provide a method for the easy insertion of the patello-femoral prosthesis.

These and additional objects are met by the use of a prosthetic system comprising a patellar prosthesis and a femoral prosthesis. The patellar prosthesis replaces the femoral surface of the patella with a convex prosthesis constructed from a low-friction material. The femoral prosthesis replaces the trochlear groove of the femur with an elongate prosthesis having a trough-like

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indentation in its upper surface for the patellar prosthesis to ride in. The femoral prosthesis has spreading apart vanes protruding from a lower surface thereof. The vanes and the lower surface are of a biocompatible material that promotes bonding to living bone. The femoral prosthesis is inserted by first
5 driving a guide rod into the distal end of the femur. The rod is then used to position a guide frame which directs an instrument in cutting a groove in the trochlear portion of the femur. Then a second guide frame replaces the first frame and is used as a template for cutting slots sized to receive the vanes of the prosthesis. Finally, after removing the frame and rod, the prosthesis is slid
10 into the cut groove with the vanes sliding into and occupying the slots. The prosthesis is fixed in place with an implant peg and, over time, the interaction of the bone with the vanes results in tight integration of the prosthesis so that it cannot become loosened.

15

BRIEF DESCRIPTION OF THE DRAWINGS

The exact nature of this invention, as well as its objects and advantages, will become readily apparent upon reference to the following detailed description when considered in conjunction with the accompanying drawings, in which like reference numerals designate like parts throughout the
20 figures thereof, and wherein:

Figure 1 is a diagrammatic view of a cross-section of a distal end of a human femur showing the knee joint;

Figure 2 shows a cross-sectional view of a patellar prosthesis used in the present invention;

25 Figure 3 shows a perspective view of an upper surface of a femoral prosthesis of the present invention;

Figure 4 shows a cross-section of the prosthesis of Figure 3;

Figure 4A shows an alternate embodiment of the prosthesis;

30 Figure 5 illustrated insertion of a guide rod according to the method of the present invention;

Figure 6 illustrates insertion of a router guide frame of the method of the present invention;

Figure 7 illustrates the use of the router guide frame of Figure 6;

Figure 8 shows the effect of the router;

35 Figure 9 illustrates insertion and use of a vane guide frame of the method of the present invention;

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Figure 10 illustrates insertion of the femoral prosthesis of the present invention;

Figure 11 shows drilling a hole for an implant peg; and

Figure 12 illustrates fixing the femoral prosthesis with the implant
5 peg.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description is provided to enable any person skilled
10 in the art to make and use the invention and sets forth the best modes contemplated by the inventor of carrying out his invention. Various modifications, however, will remain readily apparent to those skilled in the art, since the generic principles of the present invention have been defined herein specifically to provide a patello-femoral prosthesis to replace the patello-femoral surfaces of
15 a knee joint.

Figure 1 shows a diagram of the distal end of a human femur 2. As already explained, a trochlear region 4 of the femur 2 interacts with a proximal region 8 of a tibia 6 to comprise a knee joint 1. The knee joint 1 also comprises a separate patella 3 or knee cap which is held in place by tendons
20 and ligaments 5. The patella 3 forms part of the mechanical structure of the joint as the various tendons transfer mechanical forces from the muscles (not shown) to the patella 3. The patella 3 moves in relation to the bones of the leg by sliding up and down in a trochlear groove 7 as the knee flexes and extends.

The present invention is directed towards solving knee problems
25 caused by a loss of smooth, unimpeded patellar sliding. The invention entails replacement of an undersurface of the patella 3 with a low-friction surface which slides in a trough-like prosthesis that replaces the trochlear groove 7 in the distal end 4 of the femur 2. Replacement of the patellar surface is well known in the art and is briefly illustrated only for the sake of completeness.

30 The femoral surface 20 (Figure 2) of the patella 3 is resected to remove any damaged tissue and to compensate for an increase of apparent patellar thickness caused by the addition of the prosthesis. The prosthetic device 28 used is shown in Figure 2. A disc-shaped base 22 bears peg-like protrusions 24. The base and protrusions are made from a biocompatible
35 material, preferably a metal, such as titanium, that can become integrated with living bone. The protrusions 24 bear ridges or other modifications to maximize their surface area and, hence, their interaction with the bone.

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The base 22 is generally round in shape and has a convex surface 26 sized to fit the femoral prosthesis 30. The femoral surface of the base 22 is covered by a low-friction plastic material such as UHMWPe (ultra high molecular weight polyethylene), which is also biocompatible. This material is joined to the base by some type of mechanical interaction. One possible method of attachment is taught by United States Patent No. 5,024,670 to Smith et al. It is important that the UHMWPe surface be convex to ride within an elongated, arcuate in cross-section indentation of a femoral prosthesis. The convex surface 26 may be entirely provided by the plastic material in which case the underlying base 22 would be planar as illustrated, or the plastic material may simply overlay and mimic the shape of a convex base (not illustrated).

The femoral prosthesis 30, as shown in Figure 3, is an improved device unique to the present invention. The device comprises an elongate member 32 with an elongate indentation 34 in its upper surface. The indentation 34 is arcuate or trapezoidal in cross-section (see Figures 4, 4A). As already mentioned, the prosthesis 30 is intended to replace the trochlear groove in which the patella 3 normally rides. To this end, at least a lower surface 42 (42') of the prosthesis 30, which contacts the living bone of the femur 2, is constructed of titanium or some other biocompatible material that is capable of forming a strong union with bone. To further enhance interaction between the prosthesis 30 and the femur 2, the device bears at least two longitudinally-oriented, spreading apart vanes 44 that project out about 2-3 cm from the elongate member 32. The vanes 44 diverge from each other (as opposed to being parallel in cross-section). Because of this divergence when the vanes 44 are inserted into slots (explained below) cut into the femur 2, the elongate member 32 is held in place by the bone surrounding the divergent vanes 44.

An upper surface of the prosthesis 30 bears the longitudinal arcuate indentation 34. The upper surface is preferably constructed from or coated with chromium or some other hard, wear-resistant material. In cross-section (Figure 4) the arcuate indentation 34 is fairly shallow. The prostheses 30 are available in various sizes depending on the size of the knee joint to be replaced. However, the average dimensions of the indentation 34 are about 3 cm wide by 8 cm long. Margins of the groove form a relatively flat lip 36. If the edges of the trough-like indentation 34 ended abruptly without the lip 36, the patellar prosthesis 28 might overrun the edge of the femoral prosthesis 30 during abnormal overextension or manipulation of the joint. Instead, the

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patellar prosthesis 28 merely rides on the flat lip 36 and is returned to the indentation 34 by ligaments and tendons 5 when the abnormal conditions cease.

At a proximal end of the indentation 34 the prosthesis 30 bears an aperture 38 for the insertion of a locking implant peg. The peg (see Figure 12) is preferably spring-loaded so that when it is inserted through the aperture 38 and tightened, it locks in place, thereby resisting accidental loosening. The implant peg is intended to mechanically fix the prosthesis 30 in place against sliding movement until the bone forms a strong union with the undersurface 42 (42') of the prosthesis 30. The vanes 44 hold the prosthesis 30 against forces normal to a long axis of the femur 2.

At a distal end the prosthesis is turned down almost at right angles to the elongate indentation. This downturned region 39 serves a function similar to the lip 36 along the edges of the trough-like indentation 34. Normally the patellar prosthesis 28 slides up and down in the indentation 34. The proximal end of the prosthesis 30 extends far enough up the femur 2 that it is impossible for the patellar prosthesis 28 to run off that end. However, it may be possible, under extreme conditions of joint motion, for the patellar prosthesis 28 to move past the distal end of the indentation 34. The downturned end 39 of the prosthesis 30 provides a smooth ramp for the patellar prosthesis 28 to return to the indentation 34 without becoming stuck at the distal end of the femoral prosthesis 30.

The prosthesis 30 is installed into the femur 2 according to the following procedure. After resection of the knee joint 1 to expose a trochlear end 52 of the femur 2, a guide rod 50 is driven into the distal end of the femur 2 (see Figure 5). A removable handle 54 aids in this process. The rod 50 is oriented parallel to the long axis of the femur 2 and serves to position several apparatuses used to install the prosthesis 30.

Next, a router guide frame 60 (see Figure 6) is inserted onto the guide rod. The guide frame 60 acts as a template which guides a router 70 which excavates the trochlear groove to make room for the prosthesis 30. After the router 70 has been used, the trochlear groove will have become an enlarged groove 80 of sufficient size to accommodate the elongate the femoral prosthesis 30.

The router guide frame 60 is removed and replaced with a vane guide frame 90 (see Figure 9). This frame 90 fits into the excavated groove 80 and is designed to guide a bone cutting saw 92 in cutting narrow slots 100 that are just the size and shape of the spreading apart prosthesis vanes 44. After the

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bone cutting saw 92 is used, the vane guide frame 90, as well as the guide rod 50, are removed, leaving an enlarged trochlear groove 80 including narrow slots 100 cut into the groove 80 and sized to accommodate the vanes 44 of the prosthesis 30.

5 As shown in Figure 10, the proximal end of the prosthesis 30 is inserted into the distal of the machined trochlear groove 80. The prosthesis 30 just fits with the vanes 44 slipping into the slots 100. Not only are the vanes 44 and slots 100 designed to increase the surface area for a bone union to form; they also ensure the proper orientation of the prosthesis 30. The vanes 44 and
10 slots 100 make it impossible for the prosthesis 30 to be inserted incorrectly or for the prosthesis 30 to tip, shift or loosen after insertion. A small mallet 102 is then used to strike the downturned distal end 39 of the prosthesis 30, sliding the prosthesis 30 all the way into the machined groove 80 with the vanes 44 sliding through the slots 100. Finally, movement of the prosthesis 30 ends
15 when a downturned end 39 contacts the distal end of the femur 2. The vanes 44 prevent the prosthesis from being lifted out of the groove 80 while the distal end 39 prevents further sliding into the femur. The prosthesis 30 is prevented from sliding out of the groove 80 by a locking peg or bone screw 110. This is accomplished by drilling a hole in the bone (Figure 4) followed by insertion of
20 the locking implant peg 110 to complete the insertion procedure (Figure 12).

 If the patellar unit 28 has not already been installed, it is installed at this juncture. The patella 3 is then reinserted into the new trochlear groove (arcuate indentation 34) and the joint is closed. No bone cement is used, so
25 there is little danger of forming a barrier of connective tissue between the bone and the prosthesis. Because there is rigid fixation by the kicking peg 100, the danger of loosening is virtually eliminated. In any case, the vanes 44 ensure that the only way to remove the prosthesis 30 is to exert a force parallel to the long axis of the femur and away from the body. The locking implant peg 110 effectively resists any tendency towards a distal sliding of the prosthesis 30. In
30 a relatively short time a union between the titanium of the prosthesis 30 and the femur 2 is formed. This union makes it virtually impossible to loosen the prosthesis 30, even without the locking implant peg 110. Therefore, the prosthesis 30 can be implanted into a young adult with every confidence that the unit will last for the life of the patient.

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Those skilled in the art will appreciate that various adaptations and modifications of the just-described preferred embodiment can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims,

5 the invention may be practiced other than as specifically described herein.

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CLAIMSWhat Is Claimed Is:

- 5 1. A method for inserting a patello-femoral prosthesis without use of bone cement comprising the steps of:
- opening a knee joint to expose a trochlear groove of a femur;
- 10 driving a guide rod into a distal end of the femur, parallel to the long axis of the femur;
- inserting a router guide frame onto the guide rod;
- using a router to cut a longitudinal groove into a distal region of the femur, size and depth of the groove controlled by the guide frame;
- 15 removing the router guide frame;
- inserting a vane guide frame onto the guide rod, the vane guide frame fitting into the groove;
- using a saw guided by the guide frame to cut diverging vane slots into sides of the groove;
- 20 removing the vane guide frame and the guide rod;
- providing an elongate femoral prosthesis with an aperture for an insertable peg near a first end and having spreading apart, non-parallel cross-sectionally, vanes of biocompatible material protruding from a lower, biocompatible surface, the vanes sized and oriented to slide into the vane slots;
- 25 sliding the first end of the femoral prosthesis into a distal end of the longitudinal groove with no use of bone cement, the vanes of the femoral component aligning with and sliding into the vane slots;
- 30 driving the femoral prosthesis into the groove by exerting force on a second end thereof until the second end of the prosthesis reaches the distal end of the groove;
- drilling a hole in the femur by inserting a drill through the aperture in the first end of femoral prosthesis;

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screwing an insertable peg through the aperture and into the drilled hole; and

closing the knee joint so that bone can adhere to the prosthesis without any bone cement.

5

2. The method of Claim 0, wherein the insertable peg is of a locking design so that it will not loosen after insertion.

3. A patello-femoral prosthesis system for replacing articulating surfaces of a patello-femoral joint, the prosthesis system comprising:

10

a patellar component dimensioned and arranged to be attached to a surface of a patella and dimensioned and arranged for facing a surface of a femur, the patellar component comprising:

15

a disc-shaped attachment piece including a plurality of pegs on a patellar surface thereof for insertion into a patella; and

20

a bearing piece attached to a femoral surface of the attachment piece and presenting a smooth, convex outer surface; and

an elongate femoral prosthesis arranged for attachment to a patellar surface of a femur without bone cement and dimensioned for replacing a trochlear groove thereof, the femoral prosthesis comprising:

25

an outer surface for facing a patella, the outer surface bearing a shallow, cross-sectionally arcuate indentation running the length of the outer surface parallel to a long axis of a femur when the femoral prosthesis is attached thereto;

30

out-turned lips forming longitudinal edges of the outer surface of the femoral prosthesis;

35

a proximal end spaced from a tibial end of a femur when the femoral prosthesis is attached thereto, the proximal end bearing an insertable peg for attaching the femoral prosthesis to a femur without bone cement and for preventing accidental loosening; and

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a distal end near a tibial end of a femur when the femoral prosthesis is attached thereto, the distal end forming a downturned edge to keep the bearing piece of the patellar component from becoming trapped;

5

an inner surface sized to fit an enlarged trochlear groove without bone cement; and

10

at least two projecting vanes, spreading apart and non-parallel cross-sectionally, borne on the inner surface, running a length thereof, arranged and dimensioned to fit slots cut into a femur, for ensuring permanent adhesion of the femoral prosthesis by directly contacting bone without bone cement when the femoral prosthesis is affixed to a femur.

15

4. The prosthesis system of Claim 0, wherein at least the inner surface and vanes of the femoral prosthesis are constructed of a biocompatible material that promotes union to bone.

20

5. The prosthesis system of Claim 0, wherein the insertable peg is of a self-locking design so that it cannot become loosened after being once inserted.

25

6. An elongate patello-femoral prosthesis for replacing a femoral surface of a patello-femoral joint and dimensioned and arranged for replacing a trochlear groove without bone cement, the prosthesis comprising:

30

an outer surface facing a patella when the prosthesis is attached to a femur, the outer surface bearing a shallow, cross-sectionally arcuate indentation running the length of the outer surface parallel to the long axis of a femur when the prosthesis is attached thereto;

an inner surface facing a femur when the prosthesis is attached thereto, the inner surface composed of biocompatible material, and sized to fit an enlarged trochlear groove without use of bone cement;

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a proximal end spaced from a tibial end of a femur when the femoral prosthesis is attached thereto, the proximal end bearing an insertable peg for attaching the femoral prosthesis to a femur and for preventing accidental loosening; and

5 at least two vanes, spreading apart and non-parallel cross-sectionally, projecting from the inner surface of the prosthesis, the vanes running substantially a length thereof, and constructed of a biocompatible material for ensuring adhesion without bone cement by directly contacting bone when the prosthesis is
10 attached to a femur.

7. The prosthesis of Claim 0, wherein the biocompatible material of the inner surface and the vanes is titanium.

15 8. The prosthesis of Claim 0, wherein the insertable peg is of a self-locking design so that it cannot be removed after being once inserted.

9. The prosthesis of Claim 0, wherein the indentation is surrounded by a substantially flat out-turned lip for preventing a patellar
20 prosthesis from overrunning a longitudinal edge of the femoral prosthesis.

10. The prosthesis of Claim 0, wherein the prosthesis also bears a downturned distal end for preventing a patellar prosthesis from overrunning the distal end of the femoral prosthesis.

25

11. A prosthesis for insertion into a femur without bone cement to replace a femoral surface of a patello-femoral joint, the prosthesis being an elongate member comprising:

30 an outer surface facing a patella when the prosthesis is inserted into a femur, the outer surface bearing a shallow, cross-sectionally arcuate indentation running the length of the outer surface parallel to a long axis of a femur when the prosthesis is inserted therein, the indentation being surrounded by a substantially flat out-turned lip for preventing a patellar prosthesis from
35 overrunning a longitudinal edge of the femoral prosthesis;

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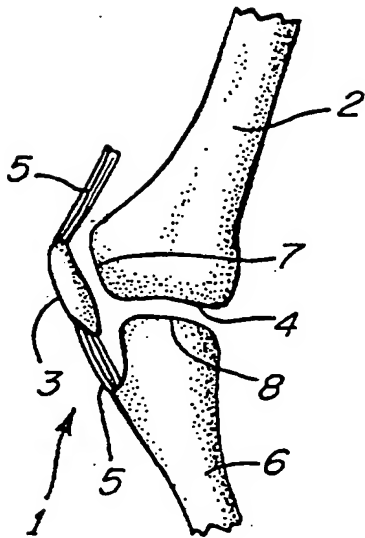
a proximal end spaced from a tibial terminus of a femur when the prosthesis is inserted therein, the proximal end bearing an insertable locking peg for attaching the prosthesis to a femur and for preventing accidental loosening;

5 a downturned distal end, opposite the proximal end, for preventing a patellar prosthesis from overrunning the distal end of the femoral prosthesis;

10 an inner surface facing a femur when the prosthesis is inserted into a femur, the inner surface composed of biocompatible titanium, and sized and arranged to slide longitudinally into a groove cut in a trochlear region of a femur without bone cement; and

15 two vanes, spreading apart and non-parallel to each other cross-sectionally, projecting from the inner surface of the prosthesis, the vanes running substantially a length thereof, and constructed of a biocompatible titanium for ensuring orientation of the prosthesis by fitting into slots cut in a femur and adhesion of the prosthesis without bone cement by directly contacting bone.

FIG. 1



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FIG. 2

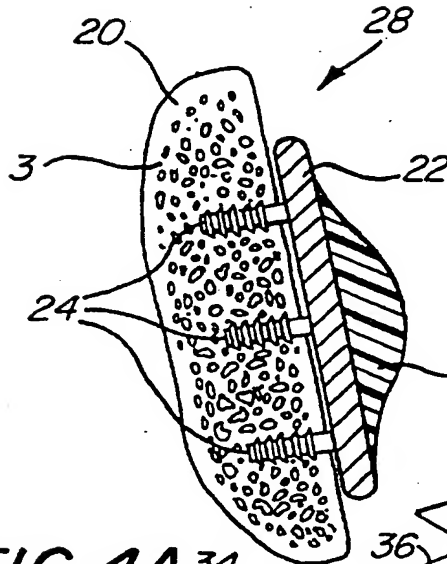


FIG. 3

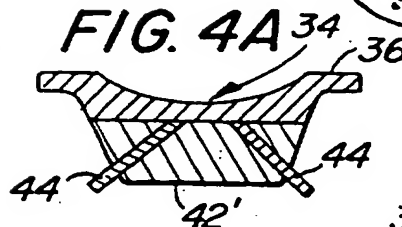
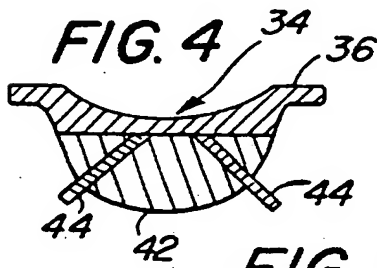
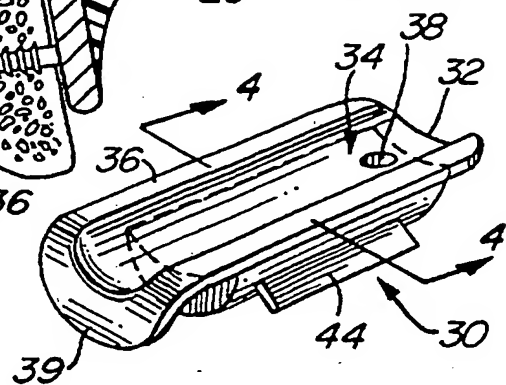


FIG. 5

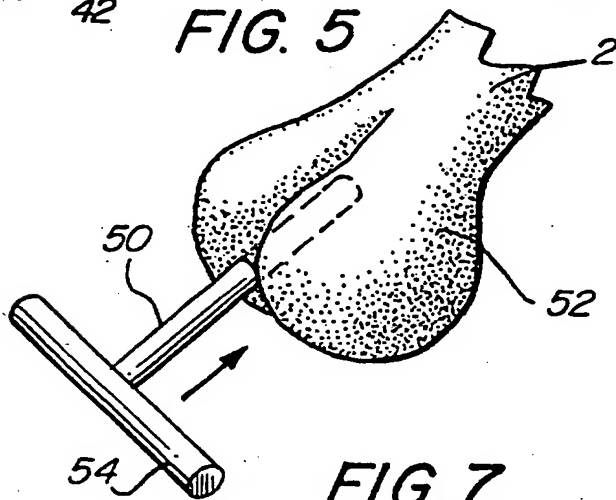


FIG. 6

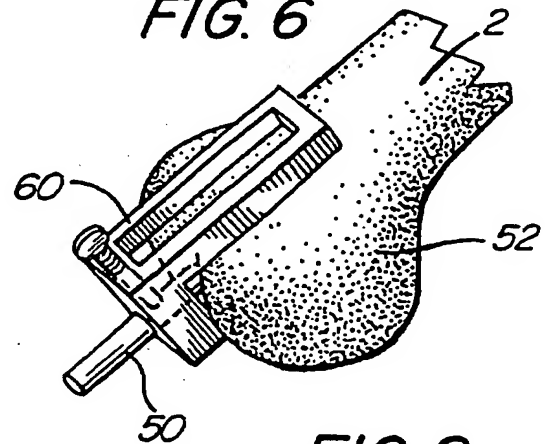


FIG. 7

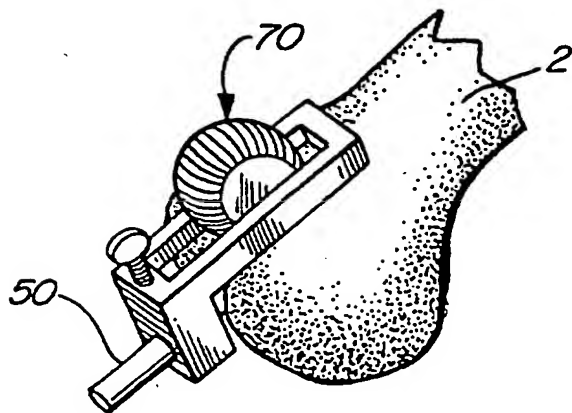


FIG. 8

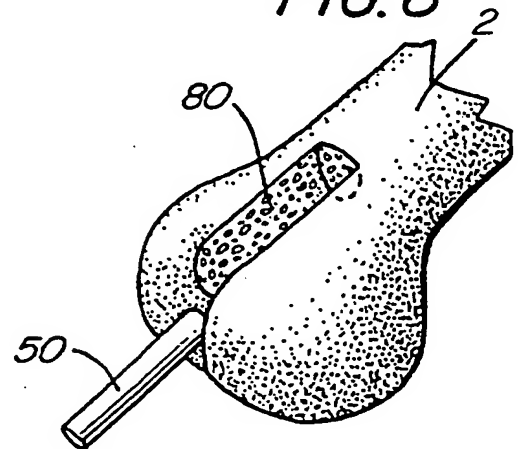


FIG. 9

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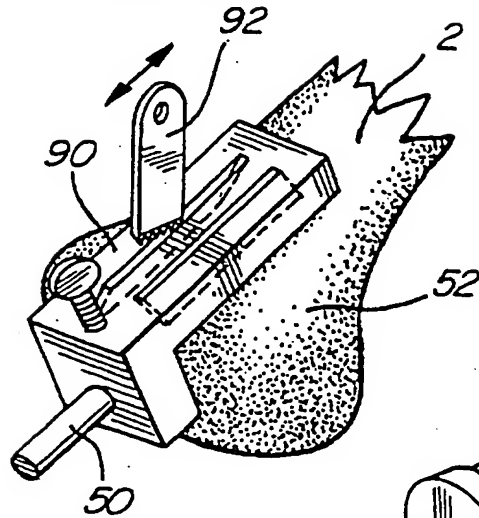


FIG. 10

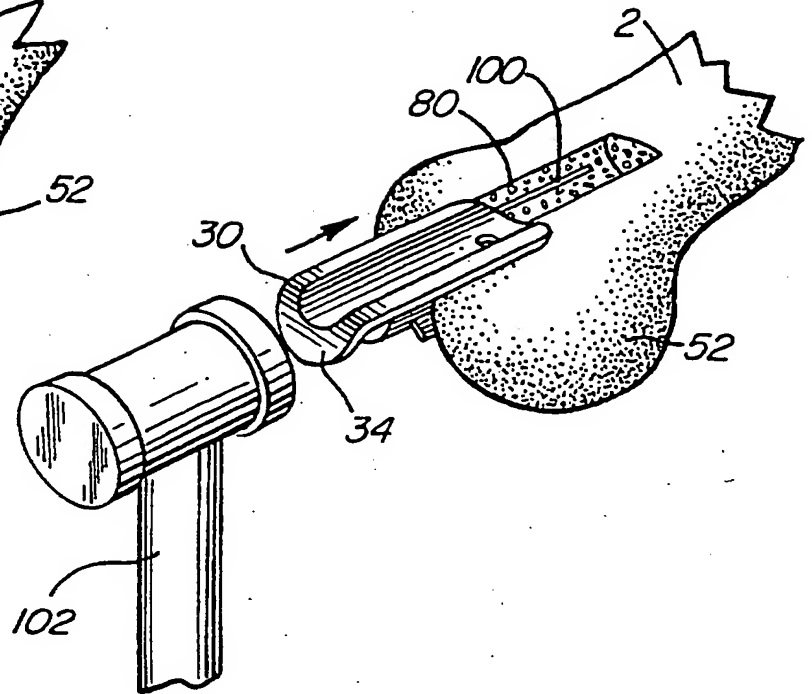


FIG. 11

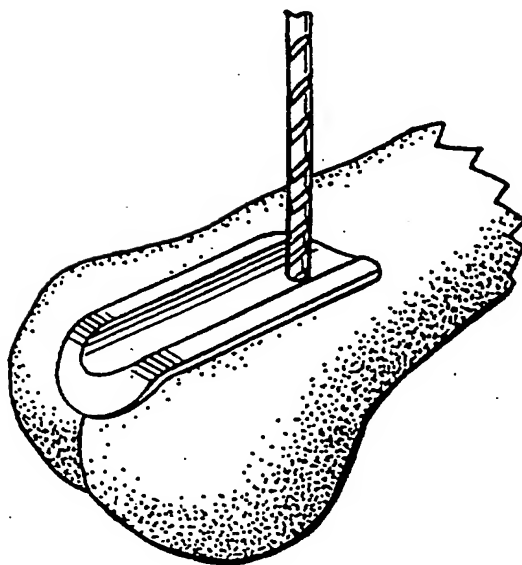
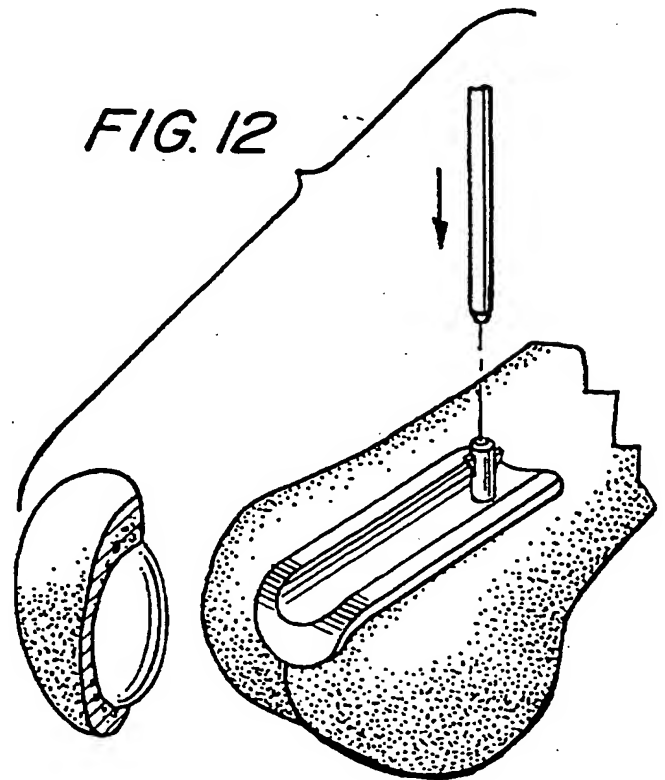


FIG. 12



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/07643

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61F2/38 A61B17/15 A61B17/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 652 497 A (MENDOLIA GEORGES) 5 April 1991 see claim 1; figures 1,2 ---	3,6,11
A	FR 2 589 720 A (AUBANIAC JEAN) 15 May 1987 see page 4, line 11 - line 20; figures 2-4 ---	3,6,11
A	EP 0 622 056 A (MEDEVELOP AKTIEBOLAG) 2 November 1994 see abstract; figures 22-33 ---	3,6,11
A	US 4 979 957 A (HODOREK ROBERT A) 25 December 1990 see abstract ---	3,6,11
A	FR 2 721 202 A (LABOURDETTE PATRICK MARIE CROL) 22 December 1995 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

28 January 1997

Date of mailing of the international search report

03. 02. 97

Name and mailing address of the ISA

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Authorized officer

Villeneuve, J-M

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 96/07643

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1,2
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 96/07643

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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FR-A-2589720	15-05-87	AU-A- 6624686 EP-A- 0245410 WO-A- 8702882	02-06-87 19-11-87 21-05-87
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FR-A-2721202	22-12-95	EP-A- 0687448	20-12-95

Form PCT/ISA/210 (patent family annex) (July 1992)